

IVD



Clinical Microbiology

MALDI Biotyper[®]

- Changing Microbiology



In Microbiology, Speed and Accuracy Matter

The MALDI Biotyper[®] System

A powerful technology for better results

To help answer key challenges in Clinical Microbiology, Bruker has utilized its many years of experience to create the truly groundbreaking MALDI Biotyper System. This revolutionary technology has allowed both large reference laboratories and small hospital laboratories to achieve reliable and efficient identification of clinically significant gram-negative bacteria, gram-positive bacteria, and yeast within an easy to operate, yet powerful benchtop analyzer.

- Accuracy comparable to Nucleic Acid Sequencing
- Much faster than traditional methods
- Cost-effective
- Robust and easy to use
- A true benchtop system
- Easy to implement
- Optional workflow improvement tools

Identifying microorganisms by their molecular fingerprint

The MALDI Biotyper System identifies microorganisms using MALDI-TOF (Matrix-Assisted Laser Desorption/Ionization Time of Flight) mass spectrometry to determine a unique proteomic fingerprint of an organism. Specifically, the MALDI Biotyper System measures highly abundant proteins that are found in all microorganisms.

The characteristic patterns of these proteins are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive IVD-CE certified reference library.

But there's more. The outstanding capabilities of the system go well beyond microbial identification and Bruker is continuously working on further innovations.

A Simple Procedure for a Sophisticated Platform

Innovative design leads to enhanced performance and productivity

The MALDI Biotyper System workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

Typically, no more than an isolated single colony from a culture plate is required.

Our dedicated microbiology software automates the process of acquiring the mass spectrum and performing the match against the extensive IVD-CE certified reference library. The results, presented using a 'traffic light' color scheme, are effortless to interpret.

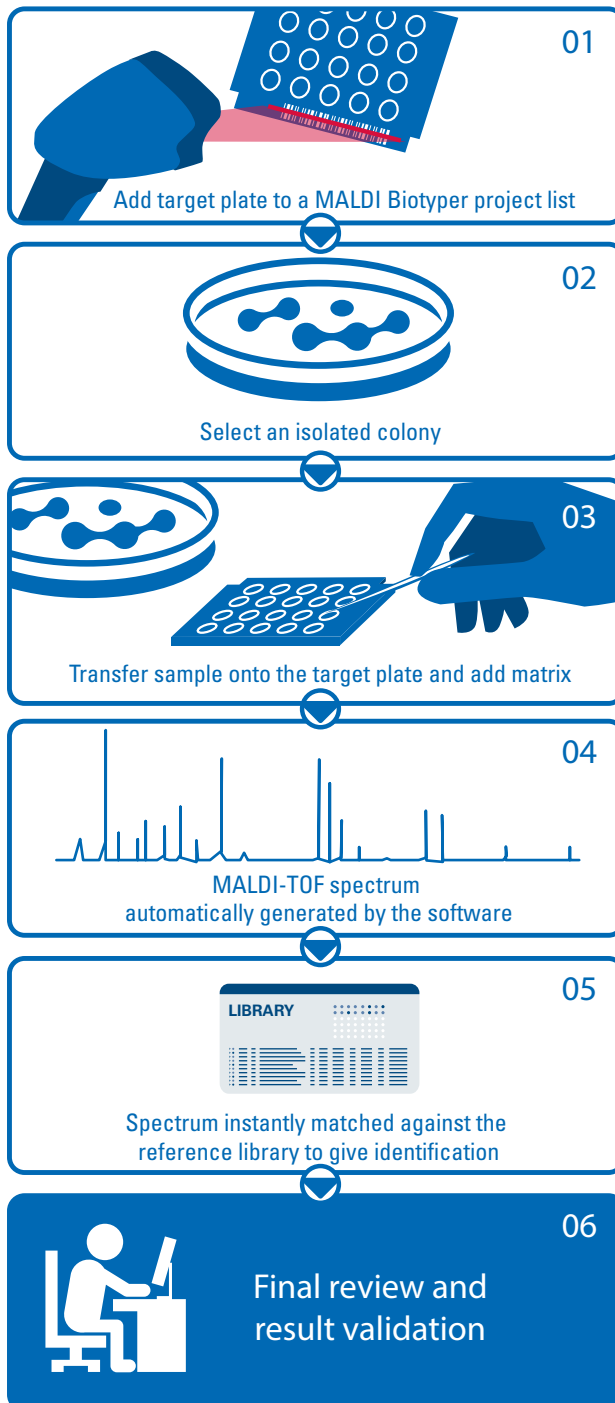
The hands-on time per isolate is only 20 seconds for 95% of the microorganisms. The short time-to-result allows preparation and analysis of a full 96-spot target plate in less than one hour.

Sample preparation hands-on time:

- 1 isolate ~20 seconds
- 95 isolates < 20 min

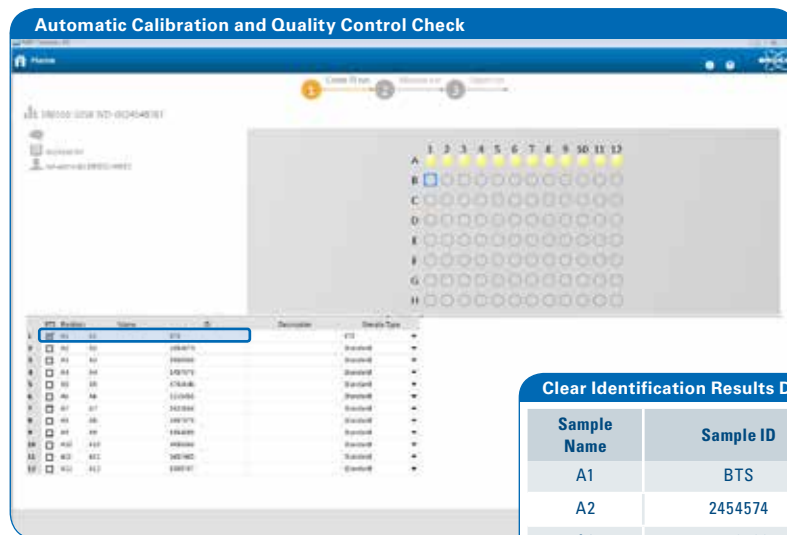
Time-to-Result including sample preparation:

- 95 isolates + 1 QC sample: < 40 min



Easy-to-Use Software that is Dedicated to Microbiology

In just a few steps, the simple-to-use software guides users through the set-up of samples for analysis.



◀ The MALDI Biotyper System is automatically checked using IVD Bacterial Test Standard (BTS) before each use. When the check is successful, the system automatically begins the measurement process.

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample is clearly listed under 'Organism (best match)' accompanied by the resulting score and appropriate 'traffic light' color scheme.

Clear Identification Results Display at Species Level

| Sample Name | Sample ID | Organism (best match) | Score Value |
|-------------|-----------|------------------------|-------------|
| A1 | BTS | Escherichia coli | 2.68 |
| A2 | 2454574 | Klebsiella pneumoniae | 2.25 |
| A3 | 5458588 | Proteus mirabilis | 2.62 |
| A4 | 5457878 | Candida albicans | 2.19 |
| A5 | 8782646 | Pseudomonas aeruginosa | 2.23 |
| A6 | 1215455 | Escherichia coli | 2.53 |
| A7 | 5423668 | Escherichia coli | 2.59 |
| A8 | 2487878 | Klebsiella pneumoniae | 2.23 |
| A9 | 5454585 | Enterococcus faecium | 2.32 |
| A10 | 4456568 | Staphylococcus aureus | 2.37 |
| A11 | 5457485 | Trueperella bernardiae | 2.47 |
| A12 | 5485787 | Candida glabrata | 2.20 |

| Range | Interpretation |
|-------------|-------------------------------------|
| 2.00 - 3.00 | High Confidence Identification |
| 1.70 - 1.99 | Low Confidence Identification |
| 0.00 - 1.69 | No Organism Identification Possible |

Easy reviewing and result validation

The informative MALDI Biotyper identification result report facilitates easy validation by the microbiologist. Subsequently, MALDI Biotyper results can be exported by a simple click in the software, in a format that a LIS or an AST system can easily understand.

Open microbiology concept - easy implementation in your laboratory

The MALDI Biotyper allows for smooth integration with existing AST systems, laboratory automation systems and laboratory informatics.

An Extensive Library - Annually Updated

Up-to-date and traceable

The integrated reference spectra library of the MBT Compass IVD software comprises spectra of thousands of strains. The library is continuously maintained and updated according to strict quality controlled procedures.

Spectra are determined from clinical isolates from collaborating partners, round robin strains and strains from strain collections.

The Main Spectra Concept

Reference library entries in the MALDI Biotyper System are stored as Main Spectra (MSP). These MSPs are based on multiple measurements of a single defined strain. To ensure that the true biological variability of an organism has been captured, MSPs of various strains of one species are included in the library.

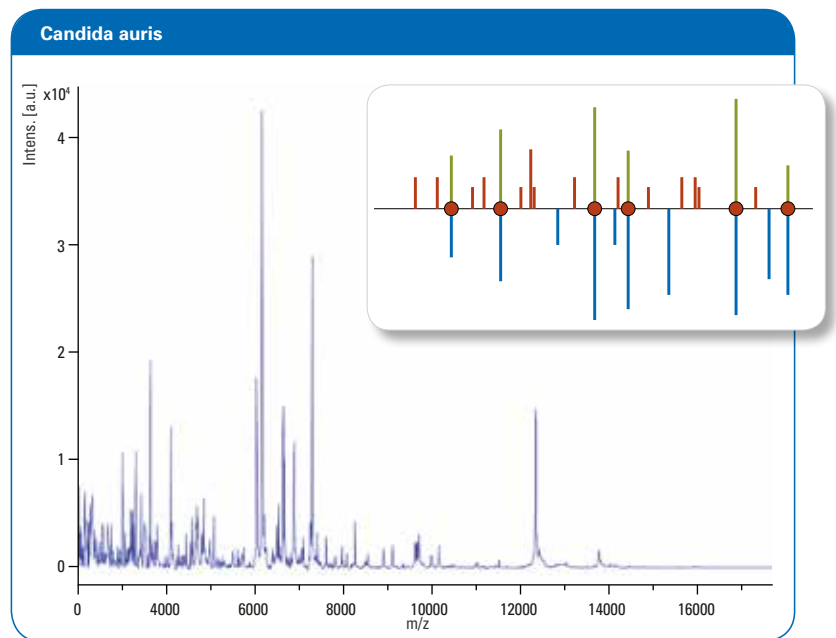
Unknowns are then compared to the MSP library using a superior pattern-matching approach. This includes peak positions and intensities, ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

Identification of highly pathogenic microorganisms

The MBT IVD Library Extension allows for early detection of highly pathogenic microorganisms in your IVD workflow, hence improving patient care, laboratory safety, and protection of public health.

High confidence mycobacteria identification

The optional MBT Mycobacteria IVD Module for the MALDI Biotyper is the comprehensive solution for highly reliable and fast mycobacteria identification. It is composed of a specific reference spectrum library and a software module. The MBT Mycobacteria IVD Library contains spectra for 178 of the currently known 201 mycobacteria species. The natural variability of *Mycobacterium* species is covered by 807 strains – of which more than 480 are clinical isolates. The MBT Mycobacteria IVD Module with adapted data acquisition and analysis secures highly sensitive and specific mycobacteria identifications.





More than just Routine Identification

Make the difference when time matters

With the optional Rapid Sepsityper workflow, Bruker is addressing the need for fast and accurate solutions to achieve prompt identification from Positive Blood Cultures (PBC). Obtaining an identification result within 15-20 minutes after the PBC alert allows quick reporting to the treating physicians. Sample preparation needs only some minutes of hands-on time and can conveniently be done in batches of PBC bottles.

An early resistance warning system

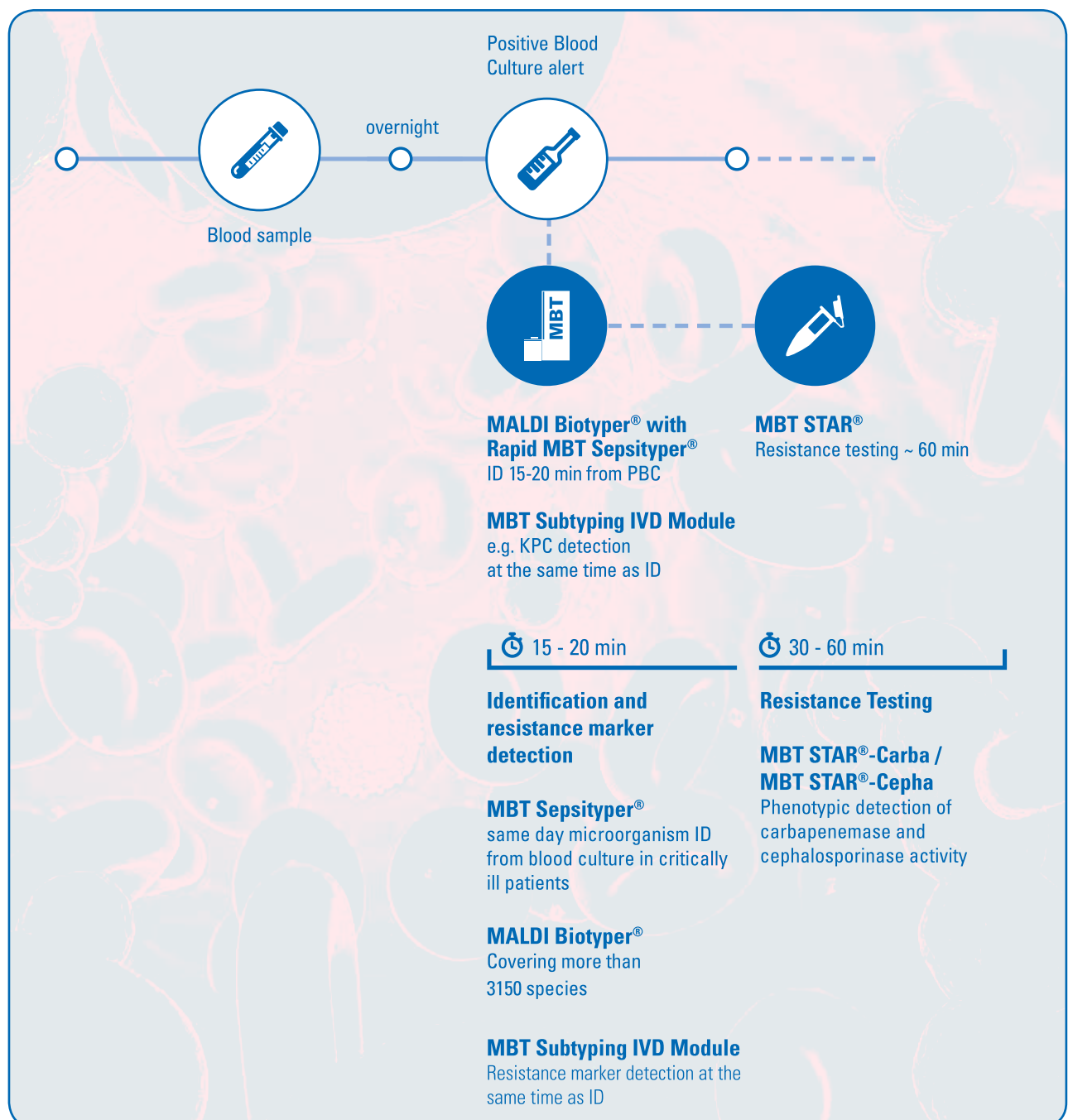
Whenever the MALDI Biotyper routine identification workflow results in successful identification of *Klebsiella pneumoniae*, *Escherichia coli* or *Bacteroides fragilis*, the optional MBT Subtyping IVD Module automatically looks for specific resistance marker peaks in the identified mass spectrum. As a result, the MBT Subtyping IVD Module quickly detects *bla*_{KPC} expressing *K. pneumoniae* and *E. coli*, and distinguishes *cfiA* positive/negative *B. fragilis* strains, giving an early resistance warning to the clinical microbiologist without any additional work.

Fast phenotypic detection of carbapenemase and cephalorinase activity

The bacterial pellet resulting from the Sepsityper workflow can subsequently be used for phenotypic detection of carbapenemase and cephalosporinase activity, within 60-90 minutes of the PBC alert, by using the MBT STAR®-Carba IVD Kit, respectively MBT STAR®-Cepha IVD Kit. The use of both kits is supported by the dedicated MBT STAR®-BL IVD Module.

Rapid and Complete Blood Culture Workflow

Fast identification after PBC alert and fast phenotypic detection of carbapenemase and cephalosporinase activity.





The Best Technology from the Experts in Mass Spectrometry

A platform suited to your needs

Being the leader in MALDI-TOF technology, it is of great importance to Bruker to design robust, compact, high performance platforms intended for extensive and routine usage in the microbiology laboratory. Continuous hardware development has led to the 4th generation of Bruker's benchtop MALDI Biotyper systems.

Bruker offers laboratories the opportunity to choose the MALDI-TOF mass spectrometer that best fits their needs:

- The new **MALDI Biotyper sirius one IVD System**, with Bruker's proprietary lifetime* smartbeam™ solid state laser technology at 200 Hz repetition rate and positive ion mode. System improvements, including the newest electronics and high performance vacuum system, generate fast target exchange times for accelerated time-to-result - even faster than before.
- The **MALDI Biotyper sirius IVD System**, with the same innovative improvements, smartbeam™ 200 Hz laser and positive as well as negative ion detection. The additional capability of analysis in negative ion mode broadens the research applications, such as the analysis of lipids (the negative ion mode is for Research Use Only).

Resolution meets sensitivity

Resolution and sensitivity are tailored to the needs of microbiologists. Due to Bruker's patented PAN™ resolution the MALDI Biotyper achieves optimal results from a compact benchtop instrument.

Highly reproducible results

The quick and simple IVD Bacterial Test Standard quality check performed before each run ensures the highest standard of run-to-run reproducibility.

Accelerated data acquisition

With Smart Spectra Acquisition™, data generation is accelerated by minimizing the number of laser shots per sample needed to acquire a meaningful spectrum. An additional benefit of this function is the optimal exploitation of the laser lifetime.

Continuous operation

The integrated ion source cleaning permits continuous high performance with minimized maintenance requirements. Cleaning the source using the separate IR-laser is performed easily under push-button operator control, without breaking vacuum.

Compact Benchtop Systems - No Performance Compromise

True benchtop solutions

Low-noise operating systems with low weight and requiring less than 1 m of counter space offer flexibility in meeting laboratory needs for compact system solutions. Both systems need only a 220 V electrical supply which results in very minimal heat output.

| | MALDI Biotyper sirius one IVD System | MALDI Biotyper sirius IVD System |
|-----------------|--|----------------------------------|
| Laser | Bruker's proprietary lifetime* smartbeam laser <ul style="list-style-type: none"> • 200 Hz repetition rate • ~400 samples/hr • 500 million laser shots | |
| Polarity | Positive ion mode only | Positive and negative** ion mode |
| Mass range | 0-500.000 Da; with MALDI Biotyper applications focused to: <ul style="list-style-type: none"> • 0-1000 Da (resistance detection) • 2.000-20.000 Da (microorganism identification) | |
| Vacuum system | High capacity turbomolecular pump <ul style="list-style-type: none"> • high pumping capacity • very fast target exchange • minimal down-time after maintenance | |
| L x W x H | 500 x 710 x 1070 mm | |
| Weight | 75 kg | |
| Common features | LED strip to remotely observe system status Perpetual Ion Source™ with IR-laser self-cleaning functionality Whispermode™ Oil-free membrane pre-vacuum pump and turbo pump <60 dB under normal operating conditions Patented PAN™ technology for high mass resolution over a wide mass range Voltage: 220 V | |

* Lifetime means: 500 million laser shots or seven years (whichever occurs first)

** Negative ion mode is for Research Use Only

MALDI Biotyper IVD System Overview

Benchtop MALDI-TOF system

- **MALDI Biotyper sirius one IVD System**, with 200 Hz smartbeam™ laser and positive ion mode or
- **MALDI Biotyper sirius IVD System**, with 200 Hz smartbeam™ laser and positive and negative ion detection (the negative ion mode is for Research Use Only)

With MALDI Biotyper data system running under Windows® 10 operating system

Routine identification of Gram +/- Bacteria, Yeasts

Software

- MBT Compass IVD software
- MBT IVD Library
- MBT IVD Library Extension

Consumables

- IVD Matrix HCCA-portioned
- IVD Bacterial Test Standard
- MBT Biotarget 96

Mycobacteria identification (optional)

- MBT Mycobacteria IVD Module

Identification directly from positive blood cultures (optional)

Software

- MBT Compass IVD Sepsityper Module

Consumables

- MBT Sepsityper IVD Kit

Resistance detection (optional)

Software

- MBT Subtyping IVD Module
- MBT STAR-BL IVD Module

Consumables

- MBT STAR-Carba IVD Kit
- MBT STAR-Cepha IVD Kit

Accessories for workflow optimization & automation (optional)

- MBT Shuttle ergonomic target holder
- MBT Pilot® for guided sample transfer
- MBT Galaxy® for automated application of matrix and formic acid
- MBT Pathfinder® IVD with Feeder option for automation of MALDI target preparation



Dimensions & Operating Parameters

MALDI Biotyper® sirius one IVD System
MALDI Biotyper® sirius IVD System

| | |
|---------------------|----------------------------|
| L x W x H: | 500 x 710 x 1070 mm |
| Weight: | 75 kg net weight |
| Noise: | < 60 dB |
| Temp Range: | 16 - 30°C |
| Operating Humidity: | 20 - 75% non-condensing |

MBT IVD Consumables for Basic Identification

IVD Bacterial Test Standard (BTS)

The BTS is an *E. coli* extract spiked with two high molecular weight proteins and has been developed for the quality control process of the MALDI Biotyper IVD System. Its specific composition covers the entire mass range of proteins used for precise identification of microorganisms.

Contents: One box consisting of 5 tubes providing 50 µL per tube / Part No 8290190



IVD Matrix HCCA - portioned

The instant HCCA matrix enables easy and convenient preparation of HCCA matrix solutions. The matrix is soluble in standard organic solvent, easy to handle, and enables highly sensitive measurements.

Contents: One box consisting of 10 tubes providing 250 µL per tube / Part No 8290200



Disposable MBT Biotargets

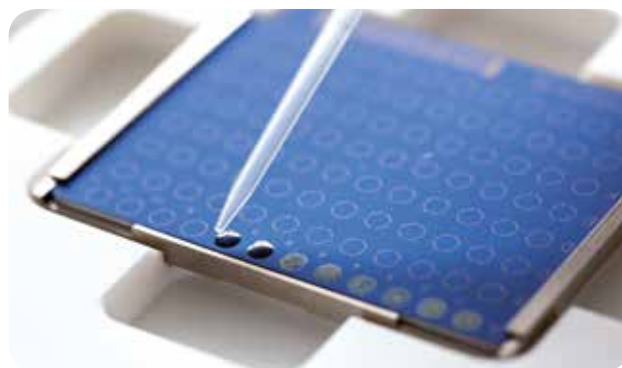
The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows. Disposable MBT Biotargets render the same level of performance as reusable MALDI target plates without the need for time-consuming cleaning.

MBT Biotarget 96

Set of 20 individually barcoded MALDI Biotyper target plates, 96 positions each / Part No. 1839298

MSP adapter for MBT Biotarget 96

Adapter required to use MBT Biotargets with microflex instruments / Part No. 8267615



MBT IVD Consumables for PBC Workflow and Resistance Detection

MBT Sepsityper® IVD Kit

The MBT Sepsityper IVD Kit contains all reagents and consumables required for microorganism isolation from 50 positive blood culture samples.

Part No. 1834338



MBT STAR-Cepha® IVD Kit

The MBT STAR-Cepha IVD Kit provides all necessary reagents and components to conduct the cephalosporinase assay.

Part No. 1858555



MBT STAR-Carba® IVD Kit

The MBT STAR-Carba IVD Kit provides all necessary reagents and components to conduct the carbapenemase assay.

Part No. 1848467



MBT IVD Workflow Accessories and Automation

MBT Shuttle Target Holder

The MBT Shuttle target holder is used to securely hold MBT Biotargets during the sample preparation process. The secure grip, non-slip rubber feet and ergonomic form make sample preparation easier.

One target holder / Part No. 1847032



MBT Pilot

The MBT Pilot facilitates correct sample positioning through patented microprojection technology by indicating the next free MALDI target plate position.

Part No. 1836006



MBT Galaxy

The MBT Galaxy frees laboratory personnel from cumbersome pipetting while ensuring the highest preparation quality under controlled conditions and complete traceability in a paperless workflow.

Part No. 1836007



MBT Pathfinder™ IVD with Feeder

The MBT Pathfinder IVD combines semi-automated colony picking with a unique sample preparation procedure of transferring the colonies onto the MALDI target plate.

Part No. 1885200





Please contact your local representative for availability in your country.
Not for sale in the USA.

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The MBT Pathfinder® is a registered trademark of Bruker Daltonik GmbH in the European Union and has been applied for trademark registration in the USA.



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